

# Exhibit 7

## MEMORANDUM OF INTERVIEW

CASE NUMBER : 2204323-MF

PERSON INTERVIEWED : Surekha Gangakhedkar

PLACE OF INTERVIEW : United States Attorney's Office, San Jose, CA

DATE OF INTERVIEW : August 29, 2019

TIME OF INTERVIEW : 2:05 P.M.

On August 29, 2019, at the United States Attorney's Office in San Jose, CA, Surekha Gangakhedkar (GANGAKHEDKAR) was interviewed regarding her knowledge of Theranos by Assistant United States Attorneys John Bostic, Robert Leach, and Jeffrey Schenk, Federal Bureau of Investigation Special Agent Cameron Purves, and me. Securities and Exchange Commission (SEC) Staff Attorney Rahul Kolhatkar participated in the interview by telephone. Present as GANGAKHEDKAR's counsel was Elizabeth Pipkin. Prior to the start of the interview, the government explained the proffer agreement to GANGAKHEDKAR, the role of the SEC in the investigation, and that she was viewed as a witness. GANGAKHEDKAR was also admonished. The following is a summary of the statements made during the interview.

GANGAKHEDKAR started her employment at Theranos in 2005 as a senior scientist and reported to Ian Gibbons. In her primary role, she developed, optimized, and tested immunoassays for Theranos' systems. In 2007, GANGAKHEDKAR was promoted to team lead of the immunoassay team. She was promoted in 2009 to assay manager and led Theranos' teams responsible for assay development. She was in the position until her resignation. During her time at Theranos, GANGAKHEDKAR also reported to Gary Frenzel (FRENZEL) and then to Elizabeth Holmes (HOLMES) when FRENZEL fell ill.

The first Theranos technology was immunoassay based. There are four major types of clinical chemistries, immunoassays being one type. CRP, HbA1C, HCG, and thyroid assays are examples of important immunoassays. Theranos eventually expanded into the other assay types, but GANGAKHEDKAR was not familiar with their development because that information was not shared with her.

Theranos' goal was to internally develop assays from scratch with reagents from commercial sources. The assays to be developed included approximately 200 from a priority list, which GANGAKHEDKAR thought was compiled by identifying the most frequently ordered CPT [current procedural terminology] code assays and by identifying the assays that were most difficult to develop.

Assays were developed for use on the Edison device using in-house donor samples and abnormal clinical blood samples, most of which were collected by venous draw. Samples were also identified to support reference ranges. These same samples were analyzed using reference systems and commercial kits. Correlation between the Edison device results and reference system results was calculated and documented in assay development reports. Strong correlation indicated development for the particular assay was complete.

Third-party devices were also used to verify that reagents were working for an assay before being further developed for the Edison device.

GANGAKHEDKAR thought Theranos wanted to develop assays that could be run more quickly and used less blood than commercial assays, and she knew Theranos wanted to develop assays using capillary blood. The volume of blood needed to run an assay depended on the target. Theranos collected blood as whole blood and serum.

Theranos' CLIA [Clinical Laboratory Improvement Amendments] lab was used to determine reference ranges. The CLIA lab could only use CLIA approved devices and methods. She did not know if Edison or Minilab devices were used in the CLIA lab.

At the time of her resignation, Theranos had developed 70 to 80 immunoassays for use on the Edison device. GANGAKHEDKAR described "validated" as an assay that is good enough to provide results to patients. While a plan was in place to validate those assays on the Edison, it had not yet been done. An assay cannot be used for patient samples if it is still in research and development (R&D) and had not been validated.

GANGAKHEDKAR described R&D as working through constantly changing conditions of an assay during its development. However, once an assay moved from R&D to a clinical setting, those conditions must be constant. Additional R&D had to be done when moving an assay to a new device, so even though an assay had been developed for the Edison, additional work needed to be done to transfer an assay to the Minilab. GANGAKHEDKAR did not know how many assays had moved out of R&D for the Minilab.

Standards were used to determine when it was appropriate to move an assay into the next stage of development. The standards were assay dependent. There was no one person in charge of this.

The Edison was not used at external sites.

The Edison cartridges were designed to use 20 microliters of blood and to multiplex two to four assays. Blood samples had to be diluted for use with the cartridge. The 3.0 version cartridge also supported two to four multiplexed assays. Multiplex cartridges required varying amounts of dilution.

Theranos assays were developed to support sample dilution with an order of magnitude ranging from five to fifty-fold. GANGAKHEDKAR stated some assays required the samples be diluted. Sample dilution proved challenging during assay development, and dilution disadvantaged an assay because it required the assay to have greater sensitivity. Assay conditions also varied at different levels of dilution. GANGAKHEDKAR said they addressed those challenges during R&D.

Theranos conducted early research with microfluidics. It did not work.

Theranos went live with Walgreens in September 2013.

GANGAKHEDKAR reviewed document THPFM0000253456 to THPFM0000253457. She stated the following regarding this document:

- The term "dark counts" referred to the device not giving a response back and "omniplex" might have referred to a protocol. GANGAKHEDKAR did not know the source of the dark counts.



- Paul Patel (PATEL) and Chinmay Pangarkar were chemistry group managers.
- Regarding the statement, “Vit D – Very noisy, Calibration curve cannot be generated” GANGAKHEDKAR was not sure if she wrote the comments following this statement in the document. The Vitamin D assay is an immunoassay that most in the industry find challenging. Vitamin D assay development was completed for the Edison.
- Calibration referred to running known standards before running unknown samples.
- GANGAKHEDKAR thought the device referred to in this email was a Minilab and not an Edison.

GANGAKHEDKAR reviewed document THPFM0000068853 to THPFM0000068854. “Sam” referred to Samarth Anekal. He typed the comments on document THPFM0000253456 to THPFM0000253457. HOLMES was involved in assay development and GANGAKHEDKAR provided either weekly or biweekly assay development updates to HOLMES and Sunny Balwani (BALWANI).

GANGAKHEDKAR reviewed document THPFM0000253442 to THPFM0000253443. “M1” referred to a specific blood sample that was run on an Edison device and in the CLIA lab. The Edison returned results of 36.8 ng/mL and CLIA returned results of 7.3 ng/mL. Tina Noyes (NOYES) expressed concern about the discordant results stating she “wonder[ed]” about the results generated in the CLIA lab. GANGAKHEDKAR thought it was troubling to see bad results generated from the CLIA lab. She did not know if there was any follow-up on this issue, or what device was used to measure Vitamin D in the CLIA lab. She did not think the device used in the CLIA lab was a Theranos device. She agreed that if there were issues with third-party devices in the CLIA lab, there were probably issues with the same devices in the R&D section of Theranos.

GANGAKHEDKAR reviewed document THPFM0000253425 to THPFM0000253426. She described the content of this document as early stage R&D prior to validation. Development of these assays on the 3.0 device had been completed and they were now going to be phased into the 4.0 device. During her time at Theranos, there were not any assays that were developed initially for the 4.0 device.

GANGAKHEDKAR reviewed document THPFM0000289730 to THPFM0000289731. The discussion in this document was focused on the time it took to run multiplex cartridges on a 3.0 device, as well as running cartridges in triplicate. In the document, (BALWANI) stated, “Heartbreaking that after 4 years this was the answer.” She did not know what he meant by the statement. The document also discussed using “lab coats.” Lab coats were covers for the Edison devices designed to keep them warm. The ambient temperature in the lab was approximately 20°C, and the Edison would not work if it was too cold. Finally, the document states, “Let me know your confidence level in the multiplexed protocols re: the below in the context of performance next to the single analyte cartridge.” She did not remember what that referred to.

The Edison devices were shown to visitors and investors during walk-throughs of Theranos’ space. HOLMES, or one of the product managers, usually led the walk-throughs. GANGAKHEDKAR, who was present for only a few of these walk-throughs and never talked, did not remember HOLMES specifically identifying to the visitors Theranos’ R&D section or the CLIA lab. GANGAKHEDKAR had no interaction with any of these visitors and was never asked to leave during a walk-through.

GIBBONS worked with PATEL in clinical chemistry.

GANGAKHEDKAR reviewed document PFM-DEPO-00008847 to PFM-DEPO-00008853. She thought this document outlined the preparation and planning for the validation of Theranos 3.5 devices.

GANGAKHEDKAR reviewed document FBI-SG-0000003. Rose Edmonds worked in the clinical group with PATEL. GANGAKHEDKAR was not sure about what was specifically being discussed in the email, but from her review of the document deduced that the Siemens machines were being modified. This was the first time she learned about the devices being modified, and was alarmed that chemistries were altered. Altered Siemens machines directly affected her work because she did not know how samples were being tested. She also did not know how the CLIA lab was operating, but assumed that CLIA devices were being operated per manufacturer specifications. She did not follow-up.

GANGAKHEDKAR reviewed document PFM-DEPO-00001221 to PFM-DEPO-00001226. GANGAKHEDKAR resigned from Theranos because she was not comfortable with the validation plan or with the use of multiple devices to complete validation. GANGAKHEDKAR was also concerned about Theranos altering device chemistries and felt that the 4.0 device and nanotainers were not working properly. In the weeks leading up to her resignation, validation of the 4.0 devices, which was Theranos' initial plan, faced challenges. GANGAKHEDKAR remembered discussing these plans with Adam Rosendorff and felt he was not concerned with the changes.

GANGAKHEDKAR reviewed document US-REPORTS-0000820 to US-REPORTS-0000821. In the document, consisting on an email, Daniel Young states, "I recommend repeating the failed runs. We will note in the study report that x number of failed runs (due to the wrong cartridges being used) were rerun." GANGAKHEDKAR adamantly stated they did not use the wrong cartridges and that the failure of the test was due to pipette and instrument hardware failure. HOLMES was copied on this email. GANGAKHEDKAR thought HOLMES received another email similar to this one regarding the 3.0 devices.

GANGAKHEDKAR said it was a huge decision for her to leave Theranos. During her brief exit interview with HOLMES, GANGAKHEDKAR raised her concerns about the system, the nanotainers, and with the timing of the Walgreens launch. She told HOLMES the 4.0 device was not ready, and the 3.5 device suffered errors. In addition, there were too many reliability issues for patient testing. HOLMES responded to GANGAKHEDKAR that she planned to draw venous blood, which surprised GANGAKHEDKAR because she understood the plan to be continued nanotainer testing. GANGAKHEDKAR thought Theranos would launch at Walgreens with the nanotainer and did not know of any plans to draw venous blood.

GANGAKHEDKAR thought HOLMES knew of the problems and was not surprised. There was no talk of delaying the Walgreens launch and it would happen as announced. NOYES shared GANGAKHEDKAR's concerns and resigned from Theranos the same day.

GANGAKHEDKAR thought HOLMES discussed her resignation with BALWANI, but BALWANI never spoke to GANGAKHEDKAR. She had limited interaction with BALWANI but described him as not approachable.



GANGAKHEDKAR thought BALWANI did not have the technical background for assay development, but HOLMES had a better understanding. GANGAKHEDKAR provided status updates at meetings BALWANI attended.

GANGAKHEDKAR was uncertain of Theranos' specific plan with the Walgreens launch, but said Theranos' wanted to conduct patient testing on Theranos devices. GANGAKHEDKAR expressed concern with using modified Siemens devices as standards and for using them to conduct patient testing. GANGAKHEDKAR was never asked to develop assays for use on modified third-party devices.

GANGAKHEDKAR said hypothetically that R&D may be involved in the modification of third-party devices depending on the scope of the modifications. Furthermore, if the CLIA lab used the devices, she would have relied on the lab to use good judgment regarding the devices' use.

GANGAKHEDKAR reviewed document THPFM0000254553 to THPFM0000254573. BALWANI expected employees to be in the lab running tests and thought GANGAKHEDKAR's team was not spending enough time in the lab, especially compared to other teams. GANGAKHEDKAR's team was also expected to help with the Edison and Minilab devices, while continuing 4.0 assay development.

GANGAKHEDKAR did not know if pharmaceutical companies validated Theranos technology or what the companies did with the data that had been generated. She remembered Theranos built a multiplex cartridge for Centocor, but did not know how they used it. She also thought she may have provided data or updates regarding this pharma work. She believed that she did not receive, draft or review any reports from pharmaceutical companies, nor did she receive, draft, or review pharmaceutical validation reports. Theranos' business development group or product managers had a greater understanding of the pharmaceutical work.

GANGAKHEDKAR reviewed document THER-2632545 to THER-2632548. Susan DiGaiimo was responsible for commercial development and probably knew of Theranos' pharmaceutical work, and Nelson Rhodes was lead for the GlaxoSmithKline (GSK) laboratory. Theranos tested samples provided by GSK for GLP at GSK with Edison devices and cartridges. GANGAKHEDKAR stated GSK also provided data they wanted used as standards for the GLP assay. She did not remember being told that GSK had validated Theranos' technology, and thought it would be hard to say that GSK had done so.

GANGAKHEDKAR thought that bulk of the work with pharmaceutical companies happened while she was at Theranos and that Theranos' last pharma work was probably with Celgene. GANGAKHEDKAR stated no one from her team went to one of the pharmaceutical companies, but she did not know if other Theranos employees had. The assays and cartridges Theranos created for the pharmaceutical companies were defined by those companies. She did not know if devices or cartridges were ever sent out.

In 2010, GANGAKHEDKAR held a team meeting with HOLMES and BALWANI. During this meeting, it was announced Theranos would pursue retail work instead of pharmaceutical work. GANGAKHEDKAR thought the genesis of this idea happened after BALWANI visited post-viral outbreak Thailand.

GANGAKHEDKAR reviewed document JAN\_000000530 to JAN\_000000531. The document states, "They are either trying to be condescending by trying to skip around answering the

concerns...” She did not know why this statement was written. “PK” is shorthand for pharmacokinetic and refers to the development of an assay for a drug. Theranos developed an assay to observe the amounts of a Johnson & Johnson drug. She said Theranos did not satisfy the requirements. GANGAKHEDKAR did not know if Theranos worked with Johnson & Johnson after this.

GANGAKHEDKAR reviewed document THPFM0000186259 to THPFM0000186260. The document states, “No work has been done yet for FS samples.” GANGAKHEDKAR thought this statement was specific to prothrombin. To her, this work is clinical chemistry and she did not know if the ELISA team examined any clotting concerns in their research.

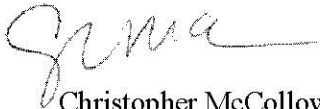
GANGAKHEDKAR reviewed document THPFM0000144275 to THPFM0000144276. The document states, “Some of the terms we clean out of the internal reports are: Tips and Edisons.” GANGAKHEDKAR said this document refers to redactions of Theranos assay development reports for internal and, probably, external uses. The reports contain significant detail about the Edison and tips and the information was considered proprietary.

GANGAKHEDKAR said a *Wall Street Journal* reporter reached out to her before the initial critical article was published, and she spoke to this reporter after the article was published. They met in-person once, and he tried to reconnect with her around the time the book was published.

During the course of the interview, we took a five minute break around 3:30 PM.

At the end of the interview, GANGAKHEDKAR was served with a trial subpoena which was accepted by her counsel.

The interview ended at 5:05 PM.



Christopher McCollow

U.S. Postal Inspector

October 31, 2019

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Date

Attachments:

- THPFM0000253456 to THPFM0000253457
- THPFM0000068853 to THPFM0000068854
- THPFM0000253442 to THPFM0000253443
- THPFM0000253425 to THPFM0000253426
- THPFM0000289730 to THPFM0000289731
- PFM-DEPO-00008847 to PFM-DEPO-00008853
- FBI-SG-0000003
- PFM-DEPO-00001221 to PFM-DEPO-00001226
- US-REPORTS-0000820 to US-REPORTS-0000821
- THPFM0000254553 to THPFM0000254573
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